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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,525	01/10/2001	Peng George Wang	10114/6	9752
757	7590	10/04/2004	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/758,525

**Applicant(s)**

WANG ET AL.

**Examiner**

Tekchand Saidha

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2003 (marked up claim copy).
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-49 and 52-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 39-49 and 52-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Group 1**

Claims 39-48 & 52-70, drawn to a transformed cell comprising – sugar nucleotide

regenerating enzyme **Galk** and a glycosyltransferase LgtB [first combination is exemplified].

**Groups 2-406 [29 X 14 = 406]**

Claims 39-48 & 52-70, drawn to a transformed cell comprising :

ONE sugar nucleotide regenerating enzyme [(from among 29 enzymes, viz., Galk or GalT or GalU or Pykf or Ndk or PpK or AcK or PoxB or Ppa or PgM or NagE or Agml or glmu or GalNAc kinase or pyrophosphorylase or Ugd or NanA or Cmk or NeuA or Alg2 or Alg1 or SusA or ManB or ManC or phosphomannomutase or GalE or GMP or GMD or GFS)] and ONE glycosyltransferase [(from among 14 enzymes, viz., LgtB, LgtC

(galactosyltransferase); Lgtf, Alg5 or DUGT (glucosyltransferase); LgtA (N-acetylglucosaminyl transferase); UDP-GalNAc:2'-fucosylgalactoside- $\alpha$ -3-N-acetylglactosaminyl transferase; UGT2B7 (glucuronyltransferase); SiaT0160 (sialyltransferase); Alg1 or Alg2 (mannosyltransferase);  $\alpha$  1,3-FucT or  $\alpha$  1,2-FucT or  $\alpha$  1,3,4-FucT (fucosyltransferases)], classified in class 435, subclass 252.3.

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**Groups 407-812** [29 X 14 = 406]

Claims 49 & 71-76, drawn to a method of producing a glycoconjugate of interest using any one of the 29 sugar nucleotide regenerating enzymes and any one of the 14 glycosyltransferase, classified in class 435, subclass 97.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-406 and 407-812 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the 406 host cell constructs [29 X14 = 406] comprise of a combination of two distinct genes. Therefore, each of the first 406 groups is patentably distinct from the other. Similarly, each of the groups 407-812, are drawn to a method of making a glycoconjugate of interest, which product when made using a distinct combination of genes encoding distinct enzymes having distinct substrate specificity would produce a compound structurally as well as functionally distinct from each other. Further, the inventions are distinct because the process as claimed can be used to make other and materially different product, such as recombinant production of the enzymes by the host cell construct, instead of producing the glycoconjugate(s) of interest.

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3. In electing a single group Applicants must identify the specific gene combination from among the 2 groups of genes encoding (a) a specific sugar nucleotide encoding enzyme and (b) a specific glycosyltransferase. Applicants must also identify if the election are to claims directed to 'host cells' [claims 39-48 & 52-70]; or to claims directed to the 'method of producing glycoconjugate'.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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September 29, 2004